

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA,

Plaintiff,

v.

AMERISOURCEBERGEN CORPORATION;
AMERISOURCEBERGEN DRUG
CORPORATION; and INTEGRATED
COMMERCIALIZATION SOLUTIONS, LLC,

Defendants.

Civ. A. No. 22-5209

**THE UNITED STATES OF AMERICA'S OPPOSITION TO
DEFENDANTS' MOTION TO COMPEL**

INTRODUCTION

Defendants’ motion is premised on a misunderstanding of the source of their liability under the Controlled Substances Act (“CSA”). The Complaint alleges that Defendants violated the CSA by negligently failing to report suspicious orders of controlled substances as required by 21 U.S.C. § 832(a). Whether an order was “suspicious” will be determined based on the statutory text of the CSA, and the reasonableness of Defendants’ failure to report suspicious orders will be assessed in light of the information Defendants had available to them about their legal obligations. Defendants nonetheless have filed this motion seeking discovery into internal DEA communications that could not possibly have informed Defendants’ decision-making. None of the documents Defendants seek to compel are relevant to the reasonableness of their conduct in failing to report suspicious orders that they identified as suspicious and did not properly investigate, or to any other issue in this case.

First, internal, non-public discussions among DEA employees about an interpretation of the suspicious-order-reporting laws (“SOR laws”) or how those laws could be amended are not relevant to determining whether Defendants acted reasonably in committing the violations of 21 U.S.C. § 832(a) at issue in this case. Indeed, multiple courts have held that internal agency documents discussing statutory or regulatory obligations are not relevant to whether a defendant acted reasonably in violating such obligations in particular instances. **Second**, purely internal deliberations among DEA employees relating to requests for guidance from industry members are not probative of whether Defendants acted reasonably in failing to report suspicious orders. Even assuming *arguendo* that the alleged lack of guidance or DEA’s “awareness” of industry uncertainty is relevant to whether Defendants’ violations of Section 832(a) were unreasonable, the Government has already agreed to produce the relevant documents on that topic—namely, the requests for guidance DEA received and any responses DEA provided. **Third**, documents about a

proposed, non-finalized rule (the 2020 SOR Notice) have no relevance to whether Defendants complied with their *statutory* obligation under 21 U.S.C. § 832(a) or whether their violations were reasonable. *Fourth*, none of the documents at issue are relevant to any other issues, including penalties, affirmative defenses, or impeachment.

BACKGROUND

Following the Court’s August 7, 2024 Order (ECF No. 82), Defendants waited until September to re-open discussions regarding their broad request for internal DEA records. When they did so, rather than engaging with the Government on the nuances that the Court directed the Parties to discuss, *see* ECF No. 82 at 5–7, Defendants requested clarification on supposedly unclear aspects of the Government’s positions, and then suggested that the Government had misled Defendants about the scope of documents it was willing to produce. *See* Ex. 1 (Sep. 13, 2024 Letter from J. Mahady). At no point did Defendants pare back or further define their “sweeping” discovery requests, ECF No. 82 at 6, propose any compromise position, respond substantively to the caselaw cited by the Government, or provide any caselaw to support their discovery demands. Though the Government repeatedly invited further engagement from Defendants consistent with the Court’s Order, Defendants instead unilaterally determined that the parties were at an impasse and filed this motion. *See* ECF No. 83-4 (Sep. 20, 2024 Letter from M. Wadden); Ex. 2 (Sep. 13, 2024–Nov. 13, 2024 email chain between M. Wadden and A. Swift).

LEGAL STANDARD

Under the Federal Rules of Civil Procedure, discovery is limited to “any nonprivileged matter that is relevant to any party’s claim or defense and proportional to the needs of the case” Fed. R. Civ. P. 26(b). The party seeking discovery has the burden to establish the relevance of the material requested. *See, e.g., Bretter v. Peyton*, No. CV 22-2509, 2023 WL

3851975, at *1 (E.D. Pa. June 6, 2023). Defendants suggest that they may unilaterally define the scope of discovery by issuing discovery requests, and they complain that the Government has raised relevance objections that are “directly at odds” with Defendants’ requests. Def. Br. at 3, 4. But Rule 26 limits discovery to matters that are *relevant* to claims or defenses and proportional to the needs of the case, and Defendants cannot redefine the scope of discovery by issuing discovery requests on whatever subjects they please.

ARGUMENT

I. The Documents Sought by Defendants Are Not Relevant to the Reasonableness of Defendants’ Conduct

Documents about Statutory Terms & Obligations (Topics A, C, and D). These Topics concern individual DEA employees’ understandings of the terms “suspicious order” and “order of interest,” and how distributors’ statutory reporting obligations applied to “suspicious orders” or “orders of interest.” Defendants claim that they drew a distinction between “suspicious orders” and “orders of interest,” that DEA personnel understood a difference between the two terms, and that Defendants are entitled to argue that their conduct “was consistent with the actions, understanding, and guidance of DEA.” Def. Br. at 7–8.

As an initial matter, Defendants misstate the Government’s case. The Complaint alleges Defendants are liable because they failed to report “suspicious orders,” as defined by the CSA, not “orders of interest,” as defined by Defendants’ policies or a never-promulgated draft regulation. Indeed, the Court has held that whether an order is suspicious “is fixed by the CSA” and “does not depend on what a given distributor says or how its system is structured.” ECF No. 47 at 17. Internal DEA documents about the meaning of “order of interest,” DEA employees’ “position” on “orders of interest,” or how the SOR laws apply to “orders of interest” (outside the context of Defendants’ own SOM programs) are irrelevant because the Government does not allege violations based on

failures to report “orders of interest” or that two-step SOM programs are incompatible with the law. Rather, the Complaint alleges that Defendants violated the CSA because they failed to report controlled-substance orders (1) that were flagged by their systems as statistically unusual, *and* (2) as to which Defendants failed to dispel suspicions as legally required. *See, e.g.*, ECF No. 1 at ¶¶ 443–485; *see also* ECF No. 47 at 16–17 (“When they receive suspicious orders, distributors must either dispel suspicion or report these orders to DEA. And the Government has plausibly alleged Amerisource failed to do so.”).

In any event, numerous courts have held that internal agency documents about the meaning of a statute or regulation are *not* relevant to whether a defendant acted reasonably in violating the law in particular instances. *See, e.g., FTC v. Amazon.com, Inc.*, No. 23-CV-0932, 2024 WL 3924583, at *4 (W.D. Wash. Aug. 22, 2024) (finding that an agency’s “internal interpretations . . . ha[ve] no bearing on the objective reasonableness of Defendants’ interpretation”); *United States v. Wisconsin Bell*, Nos. 08-C-0876, 08-C-0724, 2020 WL 13048895, at *2 (E.D. Wis., Oct. 29, 2020) (“Whether Wisconsin Bell’s interpretation of [a regulation] was reasonable depends on the statutes, regulations, and the official, public statements regarding the rule.”); *Consumer Fin. Prot. Bureau v. Navient Corp.*, No. 17-CV-101, 2018 WL 2088760, at *4 (M.D. Pa. May 4, 2018) (rejecting the defendant’s argument that internal agency discussions were relevant because they could “bea[r] on the reasonableness of [the defendants’] actions” and explaining that “[w]hat agency staff said in communication leading up to the issuance or non-issuance of rules, policies, or guidance has no bearing[.]”). Here too, internal, non-public DEA documents about the meaning of “suspicious order” or “order of interest,” or how to interpret the *Masters* decision have no bearing on whether Defendants acted reasonably. DEA is not similarly situated to Defendants, and what individual DEA employees internally thought, discussed, or interpreted with respect to the

meaning of the SOR laws is simply not relevant to whether Defendants acted reasonably or to how a “reasonable distributor” would have understood their legal obligations with respect to the orders at issue in this case. By contrast, *external* documents communicating DEA’s interpretations or understanding of the SOR laws to outside parties could bear on whether Defendants acted reasonably, and the Government has already agreed to produce such documents. ECF No. 81 at 1–2; *see also Amazon.com*, 2024 WL 3924583, at *4; *Wisconsin Bell*, 2020 WL 13048895, at *2.

Defendants attempt to distinguish these cases by asserting that they did not involve statutes with a “reasonableness” standard. *See* Def. Br. at 7 n.1. But the cases that the Government relies upon *did* involve state of mind inquiries similar to the one at issue here. For instance, *Amazon.com* involved a claim for civil penalties under the FTC Act, which are authorized only when the violative conduct is committed “with actual knowledge or knowledge fairly implied on the basis of objective circumstances that such act is unfair or deceptive and is prohibited[.]” *Amazon.com*, 2024 WL 3924583, at *3. As the *Amazon.com* court explained, a violation meets this standard when “*a reasonable person* under the circumstances would have known of the existence of the provision and that the action charged violated that provision.” *Id.* (emphasis added). And in other cases cited by the Government, the defendants argued that they had acted reasonably and that internal agency documents were relevant to that defense. *See, e.g., Navient*, 2018 WL 2088760, at *4 (rejecting defendants’ argument that internal agency documents were relevant because they bore on the reasonableness of the defendants’ actions); *Wisconsin Bell*, 2020 WL 13048895, at *2 (rejecting defendant’s argument that internal agency records were probative of whether its interpretation of a rule was reasonable).

Though some courts have held that internal agency communications are relevant to the reasonable person standard, those cases do not apply here. In *Sec. & Exch. Comm’n v. McDermott*,

the documents at issue were internal agency documents concerning the agency's investigation *of the defendants*. No. 19-CV-4229, 2022 WL 2337312, at *11–12 (E.D. Pa. June 24, 2022) (Marston, J.). Here, the Government has *already agreed* to produce such documents. ECF No. 81 at 1–2. This production includes non-privileged DEA documents discussing Defendants' systems, their use of the term "orders of interest," and their "two-step" system for order monitoring. Therefore, the Government's position is consistent with both *McDermott* and this Court's prior statements that what DEA knew about Defendants' systems and what they may have said (or not said) to Defendants about their systems may be relevant, ECF No. 75 (Jan. 22, 2024 Tr.) at 22, 26.

Defendants' reliance on *United States ex rel. Poehling v. UnitedHealth Grp., Inc.*, No. 16-CV-8697, 2018 WL 8459926 (C.D. Cal. Dec. 14, 2018), is also misplaced. As explained in *Amazon.com*, the *Poehling* decision is an outlier and does not contain any persuasive support for the position that internal agency documents are relevant to analyzing the reasonableness of a defendant's conduct. *See Amazon.com*, 2024 WL 3924583, at *4. Moreover, *Poehling* is distinguishable in that it involved reverse False Claims Act and unjust enrichment claims that implicated the Government's own interpretation of relevant laws in connection with Government reimbursement decisions, and there is no comparable Government role in relation to the violative conduct here. Finally, *Poehling* predates *Loper Bright Enters. v. Raimondo*, in which the Supreme Court further emphasized and clarified the limited relevance of agency interpretations in matters of statutory interpretation. *See Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2266 (2024) ("[A]gencies have no special competence in resolving statutory ambiguities. Courts do.").¹ In sum,

¹ In its August 7 Order, the Court noted that the Parties had not addressed whether even following *Loper Bright*, this discovery dispute may still implicate *Skidmore* deference. ECF No. 82 at 6. It does not. Even pre-*Loper Bright* informal agency interpretations in non-public internal agency documents were not entitled to any interpretive weight or deference. *See United States v. Lachman*, 387 F.3d 42, 54–55 (1st Cir. 2004) (agency employees' private thoughts are irrelevant to legal interpretation); *United States v. Farley*, 11 F.3d 1385, 1391 (7th Cir. 1993) (similar). *Loper Bright's* relevance here is that it further highlights and clarifies the limited relevance of agency employee views regarding matters of statutory interpretation.

the Court should follow *Amazon.com*, *Wisconsin Bell*, and *Navient*, and deny Defendants' sweeping requests for internal discussions among DEA employees that have no relevance to whether Defendants acted unreasonably in failing to report statutorily defined suspicious orders that their own SOM programs identified as unusual but that Defendants nonetheless failed to properly investigate or report.

Documents about General Industry Uncertainty and Lack of DEA Guidance (Topic B).

Topic B concerns documents reflecting the industry's alleged general uncertainty about suspicious-order-reporting obligations and requests for guidance from DEA. Defendants claim that evidence DEA acknowledged the suspicious-order-reporting regulation was vague would bear on the reasonableness of their own conduct. Def. Br. at 8. Once again, Defendants are mistaken.

It is clear from Defendants' motion that they contend they acted reasonably based on what they were told, or not told, by DEA. What is missing from their motion, however, is why internal, likely privileged, deliberations within DEA on whether or how to respond to requests for guidance are at all relevant to that defense. Defendants complain that the Government will not produce documents related to "*whether* to provide Defendants guidance." Def. Br. at 4 (emphasis in original). But what matters for Defendants' defense is what DEA said or did not say to Defendants and other industry players in response to requests for guidance. The Government has already agreed to produce all requests for guidance and DEA's responses (which would include Exhibit 4 to Defendants' brief). However, DEA employees' substantive internal discussions, which no third parties were privy to, are not relevant to whether Defendants acted reasonably based on the information they had. Moreover, in light of the Court's ruling on Defendants' motion to dismiss, the Government is alleging only violations of a *statutory* reporting obligation enacted by

Congress—not a regulatory obligation—so it is *Congress*’ intent that controls, thus making DEA employees’ internal deliberations doubly irrelevant.

Documents about 2020 SOR Notice (Topics A and C). Documents regarding the 2020 SOR Notice are also irrelevant. Put simply, the regulation proposed in the 2020 SOR Notice has never been finalized (as Defendants concede, Def. Br. at 3), and the only provisions at issue in this case following the Court’s decision on the motion to dismiss are 21 U.S.C. §§ 832 & 842(a)(5)—statutory provisions, not DEA regulations. A ***proposed, non-finalized*** rule has no bearing on what the statute actually in effect and at issue in this case requires and whether Defendants’ conduct was reasonable in failing to comply with the statute. Non-public musings by individual DEA employees on a rule that has not been finalized (such as those reflected in Exhibit 2 to Defendants’ brief) are simply not relevant to what the statute enacted by Congress requires.

II. The Documents Sought by Defendants Are Not Relevant to Any Other Issues

Penalties. The level of Defendants’ culpability is a relevant penalty factor, but this factor essentially comprises a *mens rea* inquiry and considers whether the defendant’s conduct was deliberate or willful. *See, e.g., Advance Pharm., Inc. v. United States*, 391 F.3d 377, 399 (2d Cir. 2004) (affirming district court’s civil penalty award where district court concluded that the reporting violations were “deliberate and persistent”). For the same reasons stated above, internal documents at DEA are not relevant to Defendants’ state of mind or the level of culpability with which Defendants committed the alleged violations because Defendants were never privy to such documents. With respect to harm (another relevant penalty factor), Defendants claim there would be no harm for failing to report orders that “DEA did not actually expect or tell Defendants to report.” Def. Br. at 9. This misstates the penalty factor, which considers the “public harm caused by the violations,” *Advance Pharm.*, 391 F.3d at 399, and in any event, the Government has already agreed to produce internal documents relating to the application of the law to Defendants.

Affirmative Defenses and Impeachment. The Government previously offered to produce internal records from specific DEA personnel whom Defendants contend provided them with advice contrary to the Government’s legal theory. *See* ECF No. 80 at 19–20 (May 17, 2024 letter from M. Wadden). However, Defendants have failed to identify any such individuals or any specific communications in which DEA provided such allegedly inconsistent advice, and their interrogatory responses and discovery correspondence suggest that [REDACTED] [REDACTED]. Ex. 3 (Defendants’ Responses to United States’ Second Set of Interrogs.); *see also* ECF No. 83-4 at 4 n.4 (Sep. 20, 2024 Letter from M. Wadden). As a result, Defendants’ request for discovery based on their vague and ill-pled affirmative defenses should be denied. In any event, even assuming Defendants’ affirmative defenses were viable, the Government has already agreed to produce all documents that could be relevant to them—including communications between DEA and Defendants and internal DEA documents that relate to such communications (*e.g.*, documents summarizing or discussing external communications). Purely internal DEA documents that do not concern Defendants and were never provided to Defendants or any party cannot be relevant to whether Defendants reasonably relied on DEA statements to their detriment.

Similarly, a theoretical possibility of impeachment does not provide a basis for expansive discovery beyond the relevant materials that the Government has agreed to produce. Defendants have not identified any particular DEA individuals whose credibility may be challenged or who Defendants believe may testify untruthfully, or offered any other basis to believe impeachment evidence even exists. The mere fact that DEA witnesses will testify does not open up all their internal records for discovery. *Sec. & Exch. Comm’n v. Collector’s Coffee Inc.*, 338 F.R.D. 309, 317 (S.D.N.Y. 2021) (“[W]hile impeachment discovery may be relevant, there must be some limit

to the general purposes of establishing credibility and gathering information for impeachment.[]If not, a party’s effort to seek impeachment material would justify nearly unlimited discovery with respect to every witness or party in every case[,] thereby vitiating the proportionality requirement.”) (internal citations and quotations omitted); *Lemanik, S.A. v. McKinley Allsopp, Inc.*, 125 F.R.D. 602, 610 (S.D.N.Y. 1989) (“In view of the breadth of the requests, some factual basis for believing that impeaching evidence will be revealed by the discovery sought is necessary.”).

III. The Documents Sought by Defendants Are Overwhelmingly Privileged

The great majority of the documents sought by Defendants are also likely protected by the attorney-client or deliberative process privileges. In particular, internal agency documents about the meaning of the SOR laws, statutory terms, or judicial opinions will likely be almost exclusively prepared by or for agency attorneys. Additionally, documents relating to potential amendments to the SOR laws, proposed rules, and requests for guidance from industry members are likely protected by the deliberative process privilege, which exempts from disclosure agency “documents containing confidential deliberations of law or policymaking, reflecting opinions, recommendations or advice.” *Bayliss v. New Jersey State Police*, 622 Fed. App’x 182, 185 (3d Cir. 2015) (citations and quotations omitted). Given that the great majority of the documents at issue would be withheld on privilege grounds, the burden of searching, reviewing, and producing any non-privileged documents and logging the rest is disproportionate. *See In re Domestic Drywall Litig.*, No. 15-CV-1712, 2016 WL 4414640, at *8 (E.D. Pa. Aug. 8, 2016) (Baylson J.) (denying motion to compel due to limited relevance and because requested “discovery would likely heavily involve, if not exclusively involve, privileged material and attorney work-product”).

CONCLUSION

For the foregoing reasons, the Government respectfully submits that the Court should deny Defendants’ motion to compel in its entirety.

Respectfully submitted,

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Dated: November 27, 2024

CERTIFICATE OF SERVICE

I hereby certify that on November 27, 2024, I served the foregoing upon Defendants' counsel of record via electronic mail.

/s/ Deborah S. Sohn

Deborah S. Sohn